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Applicant: Michael Webber

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Examiner: R. Nasser

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APPEAL BRIEF (REVISED)

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Remarks

Examiner Nasser telephoned attorney for applicant on March 2, 2004 and indicated that the Summary of Invention portion of applicant's January 14, 2004 Appeal Brief required references to the specification. Attorney for applicant is appreciative of this communication. This revised Appeal Brief includes such references in the Summary of Invention portion of the brief.

Real Party In Interest

The real party in interest is Pranalytica, Inc., located at 1101 Colorado Boulevard in Santa Monica, California. An assignment by Appellant Dr. Michael Webber to Pranalytica of this application was recorded on April 4, 2002 (Reel/Frame: 012771/0169).

Related Appeals and Interferences

Neither Appellant nor Appellant's assignee or attorney are aware of another Appeal or Interference that will affect or have a bearing on the Board's decision of this Appeal.

Status of Claims

Claims 1, 4-6, 8-11, 13, 14, 17-22, 24-26, 29-34, 36, 37 and 39-42 are rejected. No claims are allowed.

Status of Amendments

An Amendment that adopts an Examiner's suggested change to claim 1 in order to obviate a rejection under 35 U.S.C. § 112, second paragraph, is filed with this appeal. However, because claim 1 (and dependent claims 4-6, 8-11, 13, 14 and 17-19) are also finally rejected on various 35 U.S.C. § 103 grounds, entry of this Amendment will simplify, but not eliminate, the need for this Appeal.

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Summary of Invention

The invention is a method of analyzing alveolar breath (page 5, paragraph 0012) by measuring the light energy absorbed by a first component of breath, followed by spectroscopic measurement of a second breath component based on the concentration of the first breath component in a previous expired breath (page 6, paragraph 0017).

Most humans have a lung capacity of about 5 to 6 liters. Of this volume, only about 0.3 liters is involved with the gas exchange between blood and breath in the lungs. This exchange takes place in a portion of the lung termed the alveoli. This 0.3 liters of breath is called alveolar breath. The concentration of gas components in alveolar breath closely reflect the concentration of these same gas components in blood (page 1, paragraph 0002).

Taking as an illustrative example a situation where the first breath component is CO₂ and the second is ammonia, ammonia levels in a patient's bloodstream (and in a patient's alveoli breath) are indicative of patient renal failure and the need for dialysis. In accordance with this invention, a gas concentration of carbon dioxide is measured by light energy absorption. The threshold level for CO₂, above which alveolar breath is present, is normally 3.5 to 5.5 percent (page 9, paragraph 0026). When a threshold level of CO₂ concentration indicative of the threshold above which alveolar breath is present, 4.5 percent for example (page 6, paragraph 0015), the concentration of ammonia is taken in order to determine its concentration in the alveolar breath and a determination made if subsequent dialysis medical treatment is required (page 1, paragraph 0003). In a preferred embodiment, light absorption wavelengths are multiplexed before spectroscopic measurement (page 16, paragraph 0042).

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Issues

Two issues are presented by this Appeal.

1. May the requirement that there be disclosure support in the specification for the claimed invention under 35 U.S.C. § 112 first paragraph properly be extended to further require that the specification must support unclaimed, hypothetical situations?
2. Is there a suggestion to combine the references relied on in rejecting Appellant's claims?

ARGUMENT

A. 35 U.S.C. § 112 Rejection of Claims 5-6, 13-14, 25-26 and 36-37

The threshold concentration is the separation point between non-alveolar breath and alveolar breath (see Figure 2). As stated at page 9, claims 18-21, the threshold varies from person to person, and for CO₂ ranges from 3.5 to 5.5 percent. Claims 13, 25 and 36 describe a method where the threshold for measuring a second gas concentration is carried out when the first gas concentration is at least 3.5 percent. Claims 6, 14, 26 and 37 describe a method where the threshold is at least 4.5 percent. Thus, both of these thresholds are within the normal CO₂ threshold range. And these claimed preferred thresholds of 3.5 and 4.5 percent are clearly supported by the specification. See page 6, lines 5-7:

Where carbon dioxide is the first component, the threshold concentration preferably includes relative concentrations equal to or greater than 3.5%, and more preferably equal to or greater than 4.5%.

At pages 11-12 of the specification, paragraph 0032 describes that a threshold concentration level may be static, where the threshold is set and left at that level for subsequent breaths, or variable dependent on the concentration of the concentration profile of a previously expired breath. An

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example of a variable threshold is given where the highest concentration of CO₂ was measured at 5.5%, and the threshold was adjusted to 5.0%.

The Examiner states that the specification lacks support for claims 5-6, 13-14, 25-26, and 36-37 because:

In the instance where, *for some reason*, the previous breath's highest level was 3% of [sic] below or the lowest level was 2.5% or below, the updated threshold would be 3% or below. [Emphasis added.]

As previously pointed out, the Appellant's specification has disclosure support for thresholds of 3.5% and 4.5% at page 6, lines 5-7. 35 U.S.C. § 112, first paragraph, requires that the specification describe the invention. The invention of claims 5-6, 13-14, 25-26 and 36-37 is described in Appellant's disclosure. A threshold of 3.0 or below, referred to by the Examiner, is not claimed by claims 5-6, 13-14, 25-26 and 36-37. It is submitted that there is support for the invention of claims 5-6, 13-14, 25-26 and 36-37 as required by 35 U.S.C. § 112, first paragraph.

Moreover, it is submitted the Examiner's hypothetical factual situation is unjustified. Given that the normal threshold of CO₂ concentration between non-alveolar breath and alveolar is 3.5 to 5.5%, the highest CO₂ level is, by definition, above the threshold, and thus must be higher than 3.5%. So, a threshold of 3% or below proposed as a possibility by the Examiner would be well outside the normal range. It is submitted that not only is the Examiner's position unsupported by the legal requirements of 35 U.S.C. § 112, it is based on a hypothetical that is contrary to the generally accepted biology that demonstrates that the highest level of CO₂ is above the 3.5 to 4.5% threshold level of concentration.

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B. 35 U.S.C. § 103 Rejection of All Claims

All of the claims have been rejected on obvious grounds based on the combination of a number of references. For example, claims 30 and 41 stand rejected as obvious based on combining the following five references:

1. Gustafsson et al., U.S. Patent No. 6,038,913 combined with
2. Kiefer, U.S. Patent No. 3,830,630 combined with
3. Forrester et al., U.S. Patent No. 5,376,555 combined with
4. Culver, U.S. Patent No. 5,445,160 combined with
5. Grafton, U.S. Patent No. 6,192,261.

It is submitted that the fact that the Examiner relies on a combination of five references is itself indicative of nonobviousness.

It is believed that the Examiner has been forced to rely on so many references, because each individual reference has an admitted lack of teaching of critical features of Appellant's claimed invention. For example,

- Gustafsson "does not teach a method of ensuring that only alveolar breath components are measured" (October 9, 2003 Final Rejection, sentence bridging page 4 and 5).
- The Kiefer and Forrester combination "does not base the trigger threshold on previous measurements" (October 9, 2003 Final Rejection, page 4, lines 3-4).
- Kiefer "does not have optical or spectrophotometric measurements" (June 5, 2003 Office Action, page 2, last paragraph).

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- The Forrester and Kiefer combination “does not multiplex the optical signals” (June 5, 2003 Office Action, page 3, lines 3-4).

In addition to these admitted deficiencies in the cited prior art, it is not disputed that:

- Culver does not measure two components of breath, it simply detects a gas in breath to determine if the patient has stopped breathing.
- Grafton does not measure two components of breath either. Indeed, it does not analyze any gas in breath, and is cited by the Examiner to show a multiplexer.

While there is a single basis for an obvious rejection of claims 30 and 41, other rejected claims are rejected on alternate theories and various combinations of the five references cited above. For example, claims 20-22, 24-26, 29-30, 32-34, 36-37, 39 and 41-42 were rejected under 35 U.S.C. § 103 based on four different combinations of references:

- (a) Kiefer plus Forrester plus Culver;
- (b) Kiefer plus Forrester plus Culver plus Grafton;
- (c) Gustafsson plus Kiefer plus Forrester plus Culver; and
- (d) Gustafsson plus Kiefer plus Forrester plus Culver plus Grafton.

It is believed that it is not necessary to address each basis of rejection for each group of claims because all of the rejections share what is believed to be a common flaw in that they all are based on the Examiner's contention at page 4 of the October 9, 2003 Final Rejection that:

it would have been obvious to modify the above combination (Kiefer and Forrester) to update the threshold based on previous measurements in order to allow the device to be fine tuned to each patent (Culver).

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There is no suggestion to make such a combination of the Kiefer, Forrester and Culver references (common to all of the Examiner's § 103 rejections). Indeed, the references teach against such combination "to update the threshold."

In Kiefer, the threshold is fixed at 4.5%:

filament 17 is **purposely designed** so that a 4-1/2% CO₂ content in the breath sample causes filament 17 to unbalance the bridge of which it is a part . . . (col. 4, l. 13-15)

Thus, there is no teaching in Kiefer that the device "purposely designed" to have a fixed, static threshold of 4.5 could be modified to measure alveolar breath "based on the concentration of the first component in a previously expired breath" as disclosed and claimed by Appellant.

If the threshold were to be changed in Kiefer based on previously expelled breath, filament branch 17, specifically designed for a 4.5 threshold, would have to be removed and replaced by another filament in the electrical balance bridge capacitor between patient breaths. Stated differently, the suggested combination would render Kiefer inoperative.

Similarly, Forrester discloses a "**predetermined threshold**" (col. 5, l. 51). Forrester uses thermopile infrared detectors for measuring gas analysis, but notes that the filament sensor of Kiefer could also be used (col. 6, l. 19-23). So again, Forrester teaches a fixed predetermined threshold, and contains no suggestion that it be combined with Culver.

In re Dembiczak, 175 F.3d 544, 1560, 50 U.S.P.Q. 2d 1617 (Fed. Cir. 1999) involved an appeal of the rejection under § 103 of claims directed to plastic trash bags with a pumpkin face. The § 103 obviousness rejection was based on a combination of children's art references (Holiday and Shapiro) and conventional trash bag references. In reversing, the Federal Circuit noted that the portion of § 103 heading "at the time the invention was made" guards against entry into the

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"tempting but forbidden zone of hindsight". *Id.* at 998 (citations omitted). Specifically, the Federal Circuit noted that:

The Board's decision is limited to a discussion of the ways that the multiple prior art references can be combined to read on the claimed invention. . . . This reference-by-reference, limitation-by-limitation analysis fails to demonstrate how the Holiday and Shapiro references teach or suggest their combination with convention trash or lawn bags to yield the claimed invention. *Id.* at 1000.

And see, *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1354, 60 U.S.P.Q. 2d 1001 (Fed.

Cir. 2001) holding that:

[I]f references taken in combination would produce a "seemingly inoperative device", we have held that such references teach away from the combination and thus cannot serve as predicates for a *prima facie* case of obviousness. (Citations omitted).

It is respectfully submitted that Appellant's claims have been rejected based on entry into the forbidden zone of hindsight. There is no suggestion that the references be combined, and indeed they teach against their combination.

A copy of the claims on Appeal is attached as Exhibit A. As to claim 1, for which an Amendment has been filed with this Appeal Brief, the claim is shown indicating the current claim language and the proposed amendment.

Respectfully submitted

JONES DAY

Date: March 3, 2004

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EXHIBIT A

1. (Currently sought to be amended) A method of analyzing alveolar breath comprising:
 - expiring breath through an analysis chamber;
 - continuously monitoring a concentration of a first component of the breath by means of measuring the light energy absorbed by the first component as the breath is expired through the analysis chamber to determine when alveolar breath is in the analysis chamber; and
 - triggering at least one concentration spectroscopic measurement of a second component of the breath once the alveolar breath is in the analysis chamber, based on the concentration of the first component in a previously expired breath.
4. The method of claim 1, wherein triggering the at least one concentration measurement of the second component of the breath includes triggering the at least one concentration measurement when the concentration of the first component crosses a threshold concentration.
5. The method of claim 4, wherein the threshold concentration is at least 3.5% relative concentration of the first component.
6. The method of claim 4, wherein the threshold concentration is at least 4.5% relative concentration of the first component.
8. The method of claim 1, wherein the first component is carbon dioxide, oxygen, or water vapor.
9. The method of claim 1, wherein the second component is ammonia, nitric oxide, or a carbon dioxide isotope.

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10. The method of claim 1, wherein the second component is an element selected from one of the following chemical groups: alcohols, alkanes, and ketones.

11. A method of analyzing alveolar breath comprising:
expiring breath through an analysis chamber;
continuously measuring a concentration of a first component of the breath expired through the analysis chamber by means of measuring the light energy absorbed by the first component;

comparing each measured concentration of the first component to a threshold concentration to determine when alveolar breath is in the analysis chamber; and

triggering at least one concentration spectroscopic measurement of a second component of the breath once the alveolar breath is in the analysis chamber, based on the concentration of the first component in a previously expired breath.

13. The method of claim 11, wherein the threshold concentration is at least 3.5% relative concentration of the first component.

14. The method of claim 11, wherein the threshold concentration is at least 4.5% relative concentration of the first component.

17. The method of claim 11, wherein the first component is carbon dioxide, oxygen, or water vapor.

18. The method of claim 11, wherein the second component is ammonia, nitric oxide, or a carbon dioxide isotope.

19. The method of claim 11, wherein the second component is an element selected from one of the following chemical groups: alcohols, alkanes, and ketones.

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20. A method of analyzing alveolar breath comprising:
- expiring breath through an analysis chamber;
- passing light through the breath in the analysis chamber, the light comprising a first wavelength corresponding to a first absorption feature of a first component of the breath;
- continuously measuring absorption of the light at the first wavelength by the first component to determine when alveolar breath is present in the analysis chamber; and
- triggering at least one concentration spectroscopic measurement of the second component of the breath once the alveolar breath is in the analysis chamber, based on the concentration of the first component in a previously expired breath
- wherein the light at the first wavelength and the light at the second wavelength are multiplexed prior to entering the analysis chamber.
21. The method of claim 20, wherein the light further comprises a second wavelength corresponding to a second absorption feature of the second component.
22. The method of claim 21, wherein the light at the first wavelength and the light at the second wavelength follow substantially similar paths in the analysis chamber.
24. The method of claim 20, wherein triggering the at least one concentration measurement of the second component of the alveolar breath in the analysis chamber includes triggering the at least one concentration measurement when the concentration of the first component crosses a threshold concentration.
25. The method of claim 24, wherein the threshold concentration is at least 3.5% relative concentration of the first component.

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26. The method of claim 24, wherein the threshold concentration is at least 4.5% relative concentration of the first component.

29. The method of claim 20, wherein the first component is carbon dioxide, oxygen, or water vapor.

30. The method of claim 20, wherein the second component is ammonia, nitric oxide, or a carbon dioxide isotope.

31. The method of claim 20, wherein the second component is an element selected from one of the following chemical groups: alcohols, alkanes, and ketones.

32. A method of analyzing alveolar breath comprising:
expiring breath through an analysis chamber;
passing light through the breath in the analysis chamber, the light comprising a first wavelength corresponding to a first absorption feature of a first component of the breath;
continuously calculating a concentration of the first component of the breath by monitoring absorption of the light at the first wavelength by the first component;
comparing each calculated spectroscopic concentration of the first component to determine when alveolar breath is present in the analysis chamber; and
triggering at least one concentration measurement of the second component of the breath once the alveolar breath is in the analysis chamber, based on the concentration of the first component in a previously expired breath
wherein the light at the first wavelength and the light at the second wavelength are multiplexed prior to entering the analysis chamber.

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33. The method of claim 32, wherein the light further comprises a second wavelength corresponding to a second absorption feature of the second component.
34. The method of claim 33, wherein the light at the first wavelength and the light at the second wavelength follow substantially similar paths in the analysis chamber.
36. The method of claim 32, wherein the threshold concentration is at least 3.5% relative concentration of the first component.
37. The method of claim 32, wherein the threshold concentration is at least 4.5% relative concentration of the first component.
39. The method of claim 32, wherein triggering the at least one concentration measurement of the second component of the alveolar breath in the analysis chamber includes triggering at least one spectroscopic measurement of the second component.
40. The method of claim 32, wherein the first component is carbon dioxide, oxygen, or water vapor.
41. The method of claim 32, wherein the second component is ammonia, nitric oxide, or a carbon dioxide isotope.
42. The method of claim 32, wherein the second component is an element selected from one of the following chemical groups: alcohols, alkanes, and ketones.

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